DETAILED ACTION

This application is a national stage entry of PCT/JP05/01634, filed on 1/28/2005.

Priority

This application claims foreign priority to 2004-019496, filed on 1/28/2004. A certified copy of the application has been received.

Response to Remarks

1. Applicant's arguments, filed 1/12/2010, with respect to the rejection of claim 6 under 35 USC § 103(a) have been fully considered and are persuasive. The rejection of claim 6 under 35 USC § 103(a) has been withdrawn. In the amended claim set filed on 1/12/2010, the Applicants cancelled claims 1-5, and 7-8. Claim 6 is found to be free of the prior art. A statement of reasons for allowance of claim 6 is shown below.

Statement of Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: there exists no prior art which teaches or suggests treatment of migraine with the compound of formula (2), which is known commercially as KW-6002, or Istradefylline.

The closest prior art is Chen et. al., *J. Neuroscience*, **21**, pp. RC143(1-6), and Strong, *J. Pharmacy & Pharmacology*, **49**, p. 1260 (both of record). Chen et. al. teaches that both caffeine and KW-6002 are xanthines which function as antagonists of the adenosine A_2 receptors, while Strong teaches that caffeine is effective as an anti-migraine agent.

Fredholm et. al., *Pharmacological Rev.*, **51(1)**, pp. 83-133, (1999), teaches that the analgesic activity of caffeine, such as for treating headaches, is due to its antagonistic action at adenosine A_1 receptors. Fredholm et. al. was submitted on the IDS. Therefore, caffeine has dual activity towards adenosine A_1 and A_2 receptors, while KW-6002 is taught as being a specific antagonist towards adenosine A_2 receptors. As the analgesic activity of caffeine is taught to be a result of antagonistic activity at the adenosine A_1 receptors, and KW-6002 is antagonistic towards the adenosine A_2 receptors, but not the A_1 receptors, it would not have been prima facie obvious to one of ordinary skill in the art, at the time of the invention, to treat headache pain such as migraine with KW-6002. Claim 6 is found to be novel and non-obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Objection

3. The abstract of the disclosure (submitted on 7/26/2006) is objected to because it has 2 paragraphs. It is advised that the abstract be in the form of a single paragraph, and within 150 words or less. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 1/12/2010 was filed after the mailing date of the non-final action on 8/4/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Conclusion

5. Claim 6 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/
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